

REMARKS

Claims 21-36, 40-69, 76 and 77 are now pending in the above-referenced patent application. Applicants respectfully request further consideration of these claims, in view of the amendments set forth above and the following remarks.

Amended Claims

Claims 21, 23, 25, 27, 29, 31, 32, 34, 41-45, 52, 56, 60, 67 and 69 have each been amended. Claims 21, 23, 25, 27, 29, 31, 32, 41, 43, 45, 52, 60 and 67 have each been amended to specify that the agent is a steroidal agent. Claims 34, 44 and 69 have been amended to clarify that the antimicrobial agent is in addition to the steroidal agent. Claims 42-44 have been amended to correct dependency, and claim 56 has been amended to correct a typographical error.

No new matter has been added.

Rejection Under 35 U.S.C. § 112 (Indefiniteness)

Claims 42-44 stand rejected as indefinite for depending on claim 40 which is canceled. Applicants have amended claims 42-44 to depend upon independent claim thus obviating the rejection.

Rejections Under 35 U.S.C. § 103(a) (Helmus, Tweden, Fearnot, Myers)

The Office action rejects claims 21-36 and 41-70 under 35 U.S.C. § 103(a) based on various combinations of references.

Applicants respectfully traverse these rejections in view of the current claim amendments.

Helmus and Tweden

Claims 21, 22, 24-26, 28-30, 32, 34-36, 41, 42, 44-50, 52, 53, 56, 57, 59-67, 69 and 70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., U.S. Patent 5,447,724 ("Helmus"), in view of Tweden et al. U.S. Patent 5,895,419 ("Tweden").

Helmus discloses implantable medical devices having protective coatings applied to the devices. The protective coatings include a release polymer that defines reservoirs for incorporating an agent in a manner that permits substantially free outward release of the agent from the reservoir. The agent is released through an overlaying layer defining outward passages constructed to control the outward migration of the agent from the surface of the medical device.

Helmus also discloses that the articles may be entirely from the release polymers. These embodiments also require the overlayer and elutable component for controlling release. See Helmus, column 9, lines 41-44 and 46-48.

Tweden discloses metallic coatings, such as silver on a prosthetic device to enhance acceptability of the implantable device. Tweden states in the first sentence of the Summary, "In contrast to the use of pharmaceutical products, the present invention includes an antimicrobial metallic coating on portions of the prosthesis, usually fabric, to enhance the overall acceptability of the implanted device." Tweden, column 1, line 65-column 2, line 1. Thus, Tweden is limited to the use of metallic agents used with implantable medical devices.

The Final Office action suggests it would be obvious to combine the teachings of Helmus with those of Tweden to arrive at the claimed invention. Applicants respectfully submit that in view of the amendments to the claims to restrict the therapeutic agent to a steroidal agent, Tweden teaches away from the present invention by requiring the use of a metallic coating as opposed to use of a pharmaceutical. One of skill in the art would not be motivated to apply the teachings of Tweden to those of Helmus to incorporate a steroidal agent into a device as claimed. Instead, a combination of Helmus and Tweden would result in using a metallic component such as silver utilized in a release polymer as taught in Helmus.

For at least this reason, Applicants respectfully request the rejection be withdrawn.

Helmus, Tweden, Fearnot

Claims 23, 27, 33, 43, 51, 54, 58 and 68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus in view of Tweden and further in view of Fearnot et al. U.S. Patent 5,609,629 ("Fearnot").

As discussed above, in view of the amendments to the claims, one of skill in the art would not be motivated to combine Helmus and Tweden as Tweden teaches away from the use of steroidal in implantable medical devices. Adding the specific teachings of Fearnont to add dexamethasone is inconsistent with the explicit teaching in Tweden that it is limited to metallic agents as opposed to paharmaceuticals. Thus, in view of the amendments herein, there would be no motivation for one of skill in the art to combine the teachings of Helmus, Tweden and Fearnot.

For at least this reason, Applicants respectfully request the rejection be withdrawn.

Helmus, Tweden, Myers

Claim 31 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus in view of Tweden and further in view of Myers et al. U.S. Patent 5,716,397 ("Myers").

As discussed above, in view of the amendments to the claims, one of skill in the art

would not be motivated to combine Helmus and Tweden as Tweden teaches away from the use of steroidal in implantable medical devices. Adding the specific teachings of Myers to add a radiopaque salt does not cure the deficiency in the motivation to combine Helmus and Tweden. Thus, in view of the amendments herein, there would be no motivation for one of skill in the art to combine the teachings of Helmus, Tweden and Myers.

For at least this reason, Applicants respectfully request the rejection be withdrawn.

#### New Claims

New claims 76 and 77 have been added to recite (i) an annuloplasty ring consisting of a body portion overlaid by a polyester fabric overlayer, the body portion initially formed from a biostable polymer mixed with a releasable therapeutic agent wherein the releasable therapeutic agent provides a therapeutic effect to the fabric overlayer, and (ii) a method of making a medical sewing ring the method consisting: initially forming the annular insert by mixing a releasable therapeutic agent with a biocompatible polymer; and enclosing the annular insert in a fabric sheath; wherein the releasable therapeutic agent provides at least one therapeutic effect to the fabric sheath.

Helmus requires the use of an overlayer with an elutable agent to control release of the active from the device. This requirement is in every embodiment of Helmus and is no teaching anywhere in Helmus that the release polymer can ever be utilized without the overlayer to control release of the agent. Thus, new claims 76 and 77 which are limited only to the recited elements, are novel over Helmus.

#### Equivalents

The amendments to the claims and the arguments presented in supplemental response to the Office action have been made to claim subject matter which the Applicants regard as their invention. By such amendments, the Applicants in no way intend to surrender any range of equivalents beyond that which is needed to patentably distinguish the claimed invention as a whole over the prior art. Applicants expressly reserve patent coverage to all such equivalents that may fall in the range between applicants literal claim recitations and those combinations that would have been obvious in view of the prior art. In particular, as noted above, some of the claims have not been narrowed within the meaning of *Festo Corp. v. Shoketsu Kinzoku Kogyo*

*Kabushiki Co.*, 62 USPQ2d 1705 (2002), and Applicants are therefore entitled to the full range of equivalents with respect to each of the presently-pending claims.

Information Disclosure Statement

An Information Disclosure Statement is being filed on the date even herewith. Consideration of the pending claims is respectfully requested, in particular, in view of the newly cited references.

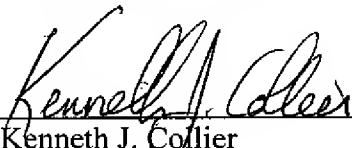
CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Examiner is hereby authorized to charge the fees required in connection with this Amendment to Deposit Account No. 13-2546, in accordance with the Transmittal submitted herewith. The Examiner is also authorized to debit any other fees required in connection with this application, or to credit any overpayment of fees in connection with this application to Deposit Account No. 13-2546.

Respectfully submitted,

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